



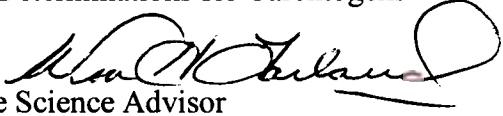
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 14 2006

OFFICE OF THE
SCIENCE ADVISOR

MEMORANDUM

SUBJECT: Implementation of the Cancer Guidelines and Accompanying Supplemental Guidance - Science Policy Council Cancer Guidelines Implementation Workgroup: Process for Internal Communication of Mutagenic Mode of Action Determinations for Carcinogens

FROM: William H. Farland, Ph.D. 
Chief Scientist, Office of the Science Advisor

TO: Science Policy Council
Science Policy Council Steering Committee

The Science Policy Council (SPC) Cancer Guidelines Implementation Workgroup (Workgroup) provides information to facilitate the development of new carcinogenicity risk assessments and to promote consistency with Agency policy, guidance, and guidelines

In its October 4, 2005, memorandum, the Workgroup provided a process for determining a mutagenic mode of action (MOA) for carcinogenicity. In Section 1C of that communication, the Workgroup concluded that communication of Agency determinations is an important step to promote consistent agency decisions and to avoid duplication of effort in these assessments. The purpose of this brief memo is to recommend a process for communication and coordination among EPA program offices and regions through the SPC Steering Committee. This communication could additionally occur through other Agency processes, such as the Action Development Process.

Chemical-specific mutagenic MOA analyses for carcinogenicity should be shared across the Agency prior to any public release. The recommended forum for sharing this information is the SPC Steering Committee, which is a cross-Agency committee composed of senior scientific and technical staff. This is not a review process, but a mechanism for sharing information with other appropriate Agency scientists and managers. The following steps are suggested:

1. Prior to the external peer review or any public release of the determination of a chemical's mutagenic mode of action for carcinogenicity, the program or region staff should notify the SPC Steering Committee via e-mail (SciencePolicy CouncilStaff@epa.gov). This notification should occur at least two weeks prior to the next scheduled SPC Steering Committee meeting, which usually is held on the second Wednesday of each month. The email should provide the following information:
 - Chemical name and Chemical Abstracts Services Registry Number (CASRN)
 - Origin (authors and office or region) and context for the MOA determination
 - Schedule for the evaluation, external peer-review and public release of the final MOA determination
 - Name of an appropriate staff member who will serve as a point-of-contact.
2. At the SPC Steering Committee meeting, the Chair may provide an opportunity for the proposing office or region to present a brief summary and discuss the determination with the SPC Steering Committee. SPC Steering Committee members may request informational copies of the scientific documentation if the notification is relevant to his/her office or region.
3. Each Steering Committee representative is responsible for ensuring that notification information is circulated to the appropriate staff within his/her program or regional office. Subsequent communication and coordination should occur among Agency staff as necessary.
4. The final decision about the determination of a chemical's mutagenic MOA for carcinogenicity also should be shared with the SPC Steering Committee via an e-mail. The following information should be provided:
 - Chemical name and CASRN
 - Final MOA determination
 - Name of appropriate staff member as a point-of-contact.

For additional information, contact the Workgroup co-chairs:
Lee Hofmann, 202 566 1928; hofmann.lee@epa.gov
Bill Sette, 202 564 0693; sette.william@epa.gov